



KANSAS DRUG UTILIZATION REVIEW NEWSLETTER

Health Information Designs, LLC

Fall 2014

Welcome to the fall 2014 edition of the "Kansas Drug Utilization Review Newsletter," published by Health Information Designs, LLC (HID). This newsletter is part of a continuing effort to keep the Medicaid provider community informed of important changes in the Kansas Medical Assistance Program (KMAP).

Updated RSV Guidelines

Palivizumab (Synagis®) is approved by the Food and Drug Administration (FDA) for the reduction of serious lower respiratory tract infection caused by respiratory syncytial virus (RSV) in children at increased risk of severe disease. Currently, a prior authorization is required for an infant or child to receive RSV prophylaxis with palivizumab. The prior authorization criteria are closely aligned with the *Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection* from the American Academy of Pediatrics (AAP) Committee on Infectious Diseases (COID).

FFS Prior Authorization Forms

The fee-for-service prior authorization forms can be found on the KDHE website at http://www.kdheks.gov/hcf/pharmacy/pharmacy_druglist_auth_forms.html.

The AAP COID has undertaken a systematic review of all recent and

older peer-reviewed literature related to the burden of RSV disease in infants and children, focusing on publications that delineate children at greatest risk of serious RSV disease and studies that define pharmacokinetics, safety, and efficacy. As part of this deliberative review of palivizumab use, the COID judged the quality of the available data, as well as the impact of palivizumab prophylaxis to reach a unanimous consensus on guidance for the use of palivizumab in the United States. Palivizumab prophylaxis has limited effect on RSV hospitalizations on a population basis, no measurable effect on mortality, and a minimal effect on subsequent wheezing.

The AAP COID policy statement offers specific guidance for the use of palivizumab on the basis of available evidence and expert opinion. The palivizumab package insert states, "Synagis is indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease." The AAP has endeavored to provide pediatricians and other healthcare providers with more precise guidance for determining who is at increased risk. The informed opinion of the COID and the Bronchiolitis Guidelines Committee, as well as others participating in the current statement, is that palivizumab use should be restricted to the populations detailed below.

Preterm Infants

Palivizumab prophylaxis may be administered to infants born before 29 weeks, who are younger than 12 months at the start of the RSV season. For infants born during the RSV season, fewer than 5 monthly doses will be needed. Palivizumab prophylaxis is not recommended in the second year of life on the basis of a history of prematurity alone.

Preterm Infants with Chronic Lung Disease (CLD)

Prophylaxis may be considered for the RSV season during the first year of life for preterm infants who develop CLD of prematurity defined as: gestational age <32 weeks, 0 days and a requirement of >21% oxygen for at least the first 28 days after birth.

During the second year of life, consideration of palivizumab prophylaxis is recommended only for infants who satisfy the definition of CLD of prematurity and continue to require medical support during the 6-month period before the start of the second RSV season. For infants with CLD who do not continue to require medical support in the second year of life, prophylaxis is not recommended. *Continued on Page 2*

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Helpful Web Sites

KMAP Web Site
<https://www.kmap-state-ks.us/>

KDHE-DHCF Web Site
<http://www.kdheks.gov/hcf/>

KanCare Web Site
<http://www.kancare.ks.gov/>

Fee-For-Service (FFS) Helpful Numbers

Provider Customer Service
(Provider Use Only)
1-800-933-6593

Beneficiary Customer Service
1-800-766-9012

KMAP PA Help Desk
1-800-285-4978

Please send questions or
comments regarding this
newsletter to
KSDURNewsletter@hidinc.com

Updated RSV Guidelines (continued)

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Infants with Hemodynamically Significant Congenital Heart Disease (CHD)

Children with hemodynamically significant CHD who are most likely to benefit from immunoprophylaxis during the first year of life include:

- Infants with acyanotic heart disease who are receiving medication to control congestive heart failure (CHF)
- Those who will require cardiac surgical procedures
- Infants with moderate to severe pulmonary hypertension

A postoperative dose of palivizumab (15 mg/kg) should be considered after cardiac bypass or at the conclusion of extracorporeal membrane oxygenation for infants and children younger than 24 months. For children younger than 2 years of age who undergo cardiac transplantation during the RSV season, palivizumab prophylaxis may be considered.

The following groups of infants with CHD are not at increased risk of RSV infection and generally should not receive immunoprophylaxis:

- Infants and children with hemodynamically insignificant heart disease
- Infants with lesions adequately corrected by surgery, unless they continue to require medication for CHF
- Infants with mild cardiomyopathy who are not receiving medical therapy for the condition
- Children in the second year of life

Children with Anatomic Pulmonary Abnormalities or Neuromuscular Disorder

Infants with neuromuscular disease or a congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough are known to be at risk for a prolonged hospitalization related to lower respiratory tract infection and, therefore, may be considered for prophylaxis during the first year of life.

Immunocompromised Children

Prophylaxis may be considered for children younger than 24 months of age who are profoundly immunocompromised during the RSV season.

Children with Down Syndrome

There is insufficient data to justify a recommendation for routine use of prophylaxis in children with Down syndrome unless qualifying heart disease, CLD, airway clearance issues, or prematurity is present.

Children with Cystic Fibrosis

Routine use of palivizumab prophylaxis in patients with cystic fibrosis is not recommended unless other indications are present. *An infant with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise in the first year of life may be considered for prophylaxis.*

Breakthrough RSV Hospitalization

If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, monthly prophylaxis should be discontinued because of the extremely low likelihood of a second RSV hospitalization in the same season.

Palivizumab Use in the Second Year of Life

A second season of palivizumab prophylaxis is not generally recommended. There are exceptions based upon the information above.

Prevention of Healthcare Associated RSV Disease

Palivizumab use is not recommended for this purpose. Infants in a neonatal unit who qualify for prophylaxis because of CLD, prematurity, or CHD may receive the first dose 48 to 72 hours before discharge from the hospital or promptly after discharge.

RSV Seasonality

Five monthly doses of palivizumab at 15 mg/kg per dose will provide more than 6 months of serum concentrations above the desired level for most children. A dose beginning in November and continuation for a total of 5 monthly doses will provide protection for most infants through April. Administration of more than 5 monthly doses is not recommended.

Reference:

American Academy of Pediatrics Committee on Infectious Disease and Bronchiolitis Guidelines Committee. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection Resource. 28 July 2014. PEDIATRICS Vol. 134 No. 2 August 1, 2014 pp. 415-420 <http://pediatrics.aappublications.org/content/134/2/415.full>

Preferred Drug List

The Preferred Drug List (PDL) is maintained by KDHE-DHCF. Each MCO and KMAP follow the same PDL. Below is a list of current preferred agents. A complete list of both preferred and non-preferred agents may be found on the KDHE-DHCF Web site. The Preferred Drug List is typically updated on the first of each month; please visit the KDHE-DHCF Web site for the most recent version: http://www.kdheks.gov/hcf/pharmacy/pharmacy_druglist.html.

Allergy, Asthma, & COPD Agents

Anticholinergics for the Maintenance of COPD

Spiriva® (tiotropium)

Combination Products for Allergic Rhinitis

Dymista® (azelastine/fluticasone)

Short-Acting Beta₂-Agonists

AccuNeb® (albuterol)

ProAir HFA® (albuterol)

Proventil® (albuterol)

Ventolin® (albuterol)

Long-Acting Beta₂-Agonists

*Clinical PA may be required

Foradil® (formoterol)

Serevent® (salmeterol)

Inhaled Long-Acting Beta₂-Agonists/Corticosteroids

Advair® (fluticasone/salmeterol)

Dulera® (formoterol/mometasone)

Symbicort® (budesonide/formoterol)

Inhaled Corticosteroids

Asmanex® (mometasone)

Flovent® (fluticasone)

Pulmicort Flexhaler® (budesonide)

Pulmicort Respules® (budesonide)

*≤6 years of age only

QVAR® (beclomethasone)

Intranasal Antihistamines

Astelin® (azelastine)

Astepro® (azelastine)

Patanase® (olopatadine)

Intranasal Corticosteroids

Flonase® (fluticasone)

Nasonex® (mometasone)

Omnaris® (ciclesonide)

Qnasi® (beclomethasone)

Zetonna® (ciclesonide)

Non-Sedating Antihistamines

Claritin® (loratadine)

Zyrtec® (cetirizine)

Ophthalmic Antihistamine/Mast Cell Stabilizer Combinations

Alaway® (ketotifen)

Pataday® (olopatadine)

Patanol® (olopatadine)

Refresh® (ketotifen)

Zaditor® (ketotifen)

Analgesics

Long-Acting Opioids

Avinza® (morphine sulfate ER)

Duragesic® (fentanyl)

MS Contin® (morphine sulfate ER)

OxyContin® (oxycodone SR)

Muscle Relaxants (Skeletal)

Flexeril® (cyclobenzaprine)

Parafon Forte DSC® (chlorzoxazone)

Robaxin® (methocarbamol)

Robaxin-750® (methocarbamol)

Robaxinal® (methocarbamol/aspirin)

Muscle Relaxants (Spasticity)

Lioresal® (baclofen)

Zanaflex® (tizanidine)

*tablets only

Ophthalmic NSAIDs

Acular® (ketorolac)

Acular LS® (ketorolac)

Acuvail® (ketorolac)

Ilevro® (nepafenac)

Nevanac® (nepafenac)

Ocufer® (flurbiprofen)

Voltaren® Ophthalmic (diclofenac)

Topical NSAIDs

Pennsaid® (diclofenac)

*branded products only

Voltaren® Gel (diclofenac)

Oral NSAIDs

Advil® (ibuprofen)

Aleve® (naproxen)

Anaprox® (naproxen)

Anaprox DS® (naproxen)

Ansaid® (flurbiprofen)

Cataflam® (diclofenac potassium)

Cloniril® (sulindac)

EC-Naprosyn® (naproxen)

Feldene® (piroxicam)

*branded products only

Indocin® (indomethacin)

Mobic® (meloxicam)

Motrin® (ibuprofen)

Motrin IB® (ibuprofen)

Naprelan® (naproxen)

Naprosyn® (naproxen)

Orudis® (ketoprofen)

Orudis KT® (ketoprofen)

Oruvail® (ketoprofen)

Relafen® (nabumetone)

Tolectin DS® (tolmetin)

Tolectin 600® (tolmetin)

Toradol® (ketorolac)

*limited to a 5 day supply

Voltaren® (diclofenac)

Voltaren® XR (diclofenac)

COX-II Inhibitors

Celebrex® (celecoxib)

Triptans

Imitrex® (sumatriptan)

*tablets only

Maxalt® (rizatriptan)

Maxalt-MLT® (rizatriptan)

Relpax® (eletriptan)

Antihyperlipidemics

Bile Acid Sequestrants

Colestid® (colestipol)

Prevalite® (cholestyramine)

Welchol® (colesevelam)

Combination Products for Hyperlipidemia

Liptruzet® (ezetimibe/atorvastatin)

Vytorin® (ezetimibe/simvastatin)

Fibric Acid Derivatives

Fenofibrate generics

Lopid® (gemfibrozil)

Statins

Lipitor® (atorvastatin)

Lovastatin generics

Mevacor® (lovastatin)

Pravachol® (pravastatin)

Zocor® (simvastatin)

HoFH Agents

Kynamro® (mipomersen)

Hypertriglyceridemia Agents

Lovaza® (omega-3 acid ethyl esters)

Anti-Infectives

Antih herpes Virus Agents

Zovirax® (acyclovir)

*oral dosage forms only

Hepatitis C Protease Inhibitors

Victrelis® (boceprevir)

Inhaled Tobramycin Products

Bethkis® (tobramycin)

Tobi® (tobramycin)

Biologics

Adult Rheumatoid Arthritis

*Clinical PA may be required

Enbrel® (etanercept)

Humira® (adalimumab)

Ankylosing Spondylitis

*Clinical PA may be required

Enbrel® (etanercept)

Humira® (adalimumab)

Crohn's Disease

*Clinical PA may be required

Humira® (adalimumab)

Juvenile Idiopathic Arthritis

*Clinical PA may be required

Enbrel® (etanercept)

Humira® (adalimumab)

Plaque Psoriasis

*Clinical PA may be required

Enbrel® (etanercept)

Humira® (adalimumab)

Psoriatic Arthritis

*Clinical PA may be required

Enbrel® (etanercept)

Humira® (adalimumab)

Ulcerative Colitis

*Clinical PA may be required

Humira® (adalimumab)

Cardiovascular Agents

ACE Inhibitors

Accupril® (quinapril)

Capoten® (captopril)

Lotensin® (benazepril)

Monopril® (fosinopril)

Prinivil® (lisinopril)

Vasotec® (enalapril)

Zestril® (lisinopril)

ACE Inhibitors/CCB Combos

Lotrel® (benzapril/amlodipine)

ARBs

Benicar® (olmesartan)

Benicar® HCT (olmesartan/HCTZ)

Cozaar® (losartan)

Diovan® (valsartan)

Diovan® HCT (valsartan/HCTZ)

Hyzaar® (losartan/HCTZ)

ARB/CCB Combos

Exforge® (amlodipine/valsartan)

Twynsta® (amlodipine/telmisartan)

Beta-Blockers

Coreg® (carvedilol)

Inderal® (propranolol)

Lopressor® (metoprolol tartrate)

Propranolol® Intensol (propranolol)

Tenormin® (atenolol)

Toprol® XL (metoprolol succinate)

CCBs (Dihydropyridines)

Adalat CC® (nifedipine ER)

Cardene® (nicardipine IR)

Norvasc® (amlodipine)

Procardia® XL (nifedipine ER)

CCBs (Non-Dihydropyridines)

Calan® (verapamil IR)

Calan® SR (verapamil SR)

Cardizem® (diltiazem IR)

Covera HS® (verapamil)

*branded products only

Diltia XT® (diltiazem)

*brand & AB-rated generics

Isoptin® SR (verapamil SR)

Tiazac® (diltiazem)

*brand & AB-rated generics

Verelan® (verapamil SR)

Central Nervous System Agents

Adjunct Antiepileptics

Keppra® (levetiracetam)

Keppra® XR (levetiracetam XR)

Lyrica® (pregabalin)

Neurontin® (gabapentin)

Zonegran® (zonisamide)

Non-Benzo Sedative Hypnotics

Ambien® (zolpidem)

Zolpidem generics

Non-Scheduled Sleep Agents

Rozerem® (remelteon)

Diabetic Agents

Alphaglucosidase Inhibitors

Glyset® (miglitol)

Biguanides

Glucophage® (metformin)

Metformin ER generics

Dipeptidyl Peptidase-4 Inhibitors

Januvia® (sitagliptin)

Onglyza® (saxagliptin)

Incretin Mimetics

*Clinical PA may be required

Bydureon® (exenatide ER)

Byetta® (exenatide)

Victoza® (liraglutide)

The list of preferred drugs is continued on page 4. This list was updated on 1/1/2015. Please visit the KDHE-DHCF Web site for the most current version. Please note that when a generic product is available for a preferred or non-preferred agent, the pharmacy will receive a lower reimbursement rate for the branded product unless a DAW PA is approved.

Preferred Drug List

Continued from page 3.

Insulin Delivery Systems

All multi-dose vials
Novolog® PenFill & FlexPen
Novolog® Mix PenFill & FlexPen

Long-Acting Insulin

Lantus® (insulin glargine)
Levemir® (insulin detemir)

Meglitinides

Prandin® (repaglinide)
Starlix® (nateglinide)

2nd Generation Sulfonylureas

Amaryl® (glimepiride)
DiaBeta® (glyburide)
Glucotrol® (glipizide)
Glucotrol® XL (glipizide XL)
Glucovance® (glyburide/metformin)
Glynase PresTab®
(micronized glyburide)
Micronase® (glyburide)

SGLT2 Inhibitors

Farxiga® (dapagliflozin)
Invokana® (canagliflozin)

Thiazolidinediones

Actos® (pioglitazone)
ACTOplus Met®
(pioglitazone/metformin)
ACTOplus Met® XR
(pioglitazone/metformin)

Gastrointestinal Agents

H₂ Antagonists

Pepcid® (famotidine)
Zantac® (ranitidine)

Oral Mesalamine Products

Delzicol® (mesalamine DR)
Pentasa® (mesalamine ER)

Pancreatic Enzyme Replacements

Creon® (pancrelipase)
Ultresa® (pancrelipase)
Viokace® (pancrelipase)
Zenpep® (pancrelipase)

Proton Pump Inhibitors

AcipHex® (rabeprazole)
Prilosec® (omeprazole)
Protonix® (pantoprazole)

Serotonin 5HT₃ Antagonists

Zofran® (ondansetron)
Zofran® ODT (ondansetron)

Gout Agents

Xanthine Oxidase Inhibitors

Zyloprim® (allopurinol)

Injectables

Erythropoiesis-Stimulating Agents

Aranesp® (darbepoetin alfa)
Epogen® (epoetin alfa)
Procrit® (epoetin alfa)

Growth Hormones

*Clinical PA may be required

Genotropin® (somatropin)
Genotropin® MiniQuick (somatropin)
Norditropin® (somatropin)
Norditropin® FlexPro (somatropin)
Norditropin® Nordiflex (somatropin)
Omnitrope® (somatropin)

Ophthalmic Agents

Ophthalmic Prostaglandin Analogs

Xalatan® (latanoprost)
Zioptan® (tafluprost)

Carbonic Anhydrase Inhibitors

Azopt® (brinzolamide)
Trusopt® (dorzolamide)

Osteoporosis Agents

Bisphosphonates

Fosamax® (alendronate)
Fosamax Plus D®
(alendronate/cholecalciferol)

Otic Combinations

Otic Combinations

Cipro HC®
(ciprofloxacin/hydrocortisone)
Ciprodex® (ciprofloxacin/dexameth)
Cortisporin® Otic
(neomycin/polymyxinB/hc)

Urologic Agents

Anticholinergic Agents

Ditropan® (oxybutynin)
Ditropan XL® (oxybutynin ER)
Toviaz® (fesoterodine)
Vesicare® (solifenacin)

Beta-3 Adrenergic Agonists

Myrbetriq® (mirabegron)

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